



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Timmermans et al.

**Serial No.:** To be assigned

**Filed:** November 3, 2003

**For:** METHOD FOR QUANTIFYING A  
RATIO BETWEEN AT LEAST TWO  
NUCLEIC ACID SEQUENCES

**Examiner:** To be assigned

**Group Art Unit:** To be assigned

**Attorney Docket No.:** 2183-5581.1US

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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of U.S. patents are not being submitted pursuant to Pre-OG Notices <<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/idswouscopies.htm>> (visited 9/15/2003). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in

37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US - 4,683,194	7-1987	Saiki et al.
US - 5,104,792	04-14-1992	Silver et al.
US - 5,106,727	04-21-1992	Hartley et al.
US - 5,607,834	3-1997	Bagwell
US - 5,948,649	09-07-1999	Stewart et al.
US - 2001021518	09-13-2001	Goudsmit et al.
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US - 6,521,428	02-2003	Senapathy
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US-6,221,600 B1	04-2001	MacLeod et al.
US-6,232,065 B1	05-2001	Robinson et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 96 15264	05-23-1996	JSD Technologies Ltd.
WO 97 30062	08-21-1997	Amsterdam Support

**Attorney Docket No.: 2183-5581.1US**

		Diagnostics B.V.
WO 98 02575	01-22-1998	Senapathy
WO 01/51661 A2	07-19-2001	Amsterdam Support
		Diagnostics B.V.
EO 0466520	01-15-1992	Life Technologies Inc.
WO 02/20571 A2	03-2002	Goudsmit et al.
WO 96/40902	12-19-1996	Trevigen, Inc.
WO 02/46470 A2	06-13-2002	Primagen B.V.
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		Ramot University Authority
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		Industrial Development, Ltd.
WO 98/17826 A1	04/30/1998	Mitokor
WO 99/66075 A2	12/23/1999	Mitokor

Other Documents

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GUO et al., Enhanced discrimination of single nucleotide polymorphisms by artificial mismatch hybridization, *Nature Biotechnology*, Vol. 15, pp. 331-335.

LEONE et al., Molecular beacon probes combined with amplification by NASBA enable homogeneous, real-time detection of RNA, *Nucleic Acids Research*, Vol. 26, No. 9, pp. 2150-55, 1998.

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TYAGI et al., Multicolor molecular beacons for allele discrimination, *Nature Biotechnology*, Vol. 16, pp. 49-53, January 1998.

ABBOTT, A.G., et al., Quantitative variation of components of the maize mitochondrial genome between tissues and between plants with different male-sterile cytoplasms, *Plant Molecular Biology* 233-40 (1985).

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BOULTWOOD J., et al., Amplification of mitochondrial DNA in acute myeloid leukaemia, *British Journal of Haematology*, 426-31 (1996).

LEE, H.K., et al., Decreased mitochondrial DNA content in peripheral blood precedes the development of non-insulin-dependent diabetes mellitus, *Diabetes Research and Clinical Practice* 161-67 (1998).

LOCKHART et al., Expression monitoring by hybridization to high

SU, C., et al., Selective reduction of creatine kinase subunit mRNAs in striated muscle of diabetic rats, *American Journal of Physiology* e310-e316 (1992).

TEPPER, C.G., "Resistance of Mitochondrial DNA to Degradation Characterizes the Apoptotic but Not the Necrotic Mode of Human Leukemia Cell Death, *Journal of Cellular Biochemistry* 352-61 (1993).

WILLIAMS R.S., Mitochondrial Gene Expression in Mammalian Striated Muscle. Evidence That Variation in Gene Dosage is the Major Regulatory Event, *J. Biol. Chem.*, 261 (26):12390-94 (1986).

WILLIAMS et al., Regulation of Nuclear and Mitochondrial Gene Expression by Contractile Activity in Skeletal Muscle, *J. Biol. Chem.*, 261(1):376-80 (1986).

VOEHRINGER et al., Gene microarray identification of redox and mitochondrial elements that control resistance or sensitivity to apoptosis. *PNAS* 97(6):2680-5 (MAR 2000).

DeRISI et al., Exploring the metabolic and genetic control of gene expression on a genomic scale, Science, 278(5338):608-6 (OCT 1997).

DeRISI et al., Use of a cDNA microarrays to analyze gene expression patterns in human cancer, Nature Genetics 14(4):457-60 (DEC 1996).

SCHENA M., Genome analysis with gene expression microarrays, Bioessays 18(5): 427-31 (1996).

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In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.: 2183-4760US  
Serial No.: 09/785,881  
Filing Date: 2/16/2001  
Title: REDUCING BACKGROUND IN HYBRIDISATION REACTIONS

Attorney Docket No.: 2183-5189US  
Serial No.: 10/006,009  
Filing Date: 12/4/2001  
Title: TESTING ENDOSYMBIONT CELLULAR ORGANELLES AND COMPOUNDS IDENTIFIABLE THEREWITH

Attorney Docket No.: 2183-5426US  
Serial No.: 10/192,786  
Filing Date: 7/10/2002  
Title: A UNIVERSAL NUCLEIC ACID AMPLIFICATION SYSTEM FOR NUCLEIC ACIDS IN A SAMPLE

Attorney Docket No.: 2183-5581US  
Serial No.: 60/425,055  
Filing Date: 11/8/2002  
Title: METHOD FOR QUANTIFYING A RATIO BETWEEN AT LEAST TWO NUCLEIC ACID SEQUENCES (DUPLEX 2)□

**Attorney Docket No.: 2183-5581.1US**

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. § 1.17(p) is required.

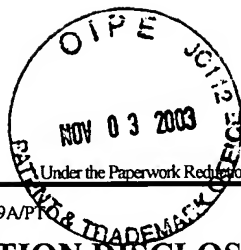
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Date: November 3, 2003  
ACT/bv

Enclosures: Form PTO-1449 or PTO/SB/08  
Cited Documents  
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PTO/SB/08A (10-01)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Sheet 1 of 3

**Complete if Known**

Application Number	To be assigned
Filing Date	November 3, 2003
First Named Inventor	Timmermans et al.
Attorney Docket Number	2183-5581.1US

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US-4,683,194	7-1987	Saiki et al.	
		US- 5,104,792	04-14-1992	Silver et al.	
		US- 5,106,727	04-21-1992	Hartley et al.	
		US- 5,607,834	3-1997	Bagwell	
		US- 5,948,649	09-07-1999	Stewart et al.	
		US- 2001021518	09-13-2001	Goudsmit et al.	
		US- 6,027,880	2-2000	Cronin et al.	
		US- 6,521,428	02-2003	Senapathy	
		US- 2003/0022194 A1	01-2003	Erlander et al.	
		US- 2003/0003488 A1	01-2003	Ramakrishnan	
		US- 2003-0099933 A1	05-2003	Cote et al.	
		US- 2002-0169562 A1	11-2002	Stephanopoulos et al.	
		US- 2002-0049176 A1	04-2002	Anderson et al.	
		US-2002-0048763 A1	04-2002	Penn et al.	
		US-5,569,754 A	10-1996	Williams et al.	
		US-6,221,600 B1	04-2001	MacLeod et al.	
		US-6,232,065 B1	05-2001	Robinson et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 96 15264	05-23-1996	JSD Technologies Ltd.		
		WO 97 30062	08-21-1997	Amsterdam Support Diagnostics B.V.		
		WO 98 02575	01-22-1998	Senapathy		
		WO 01/51661 A2	07-19-2001	Amsterdam Support Diagnostics B.V.		
		EO 0466520	01-15-1992	Life Technologies Inc.		
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		WO 96/40902	12-19-1996	Trevigen, Inc.		
		WO 02/46470 A2	06-13-2002	Primagen B.V.		
		WO 96/06191 A2	02-29-1996	Akzo Nobel N.V.		
		WO 97/39149 A1	10/23/1997	Ramot University Authority for Applied Research and Industrial Development, Ltd.		
		WO 98/17826 A1	04/30/1998	Mitokor		
		WO 99/66075 A2	12/23/1999	Mitokor		

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 3

**Complete if Known**

Application Number	To be assigned
Filing Date	November 3, 2003
First Named Inventor	Timmermans et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2183-5581.1US

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		McGRATH et al., Sequence analysis of DNA randomly amplified from the Saccharomyces cerevisiae genome, Molecular and Cellular Probes, 1998, pp. 397-405, Vol. 12.	
		ROSE et al., Consensus-degenerate hybrid oligonucleotide primers for amplification of distantly related sequences, Nucleic Acids Research, 1998, pp. 1628-35, Vol. 26, No. 7.	
		SMITH et al., Automated differential display using a fluorescently labeled universal primer, Biotechniques, 1997, pp. 274-79, Vol. 23, No. 2.	
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		MORRIS et al., Rapid Reverse Transcription-PCR Detection of Hepatitis C Virus RNA in Serum by Using the TaqMan Fluorogenic Detection System, Journal of Clinical Microbiology, Vol. 34, No. 12, pp. 2933-36, December 1996.	
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		ABBOTT, A.G., et al., Quantitative variation of components of the maize mitochondrial genome between tissues and between plants with different male-sterile cytoplasms, 4 Plant Molecular Biology 233-40 (1985).	
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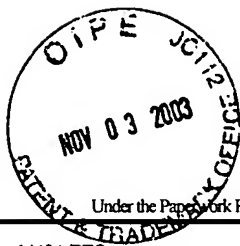
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Sheet 3 of 3

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First Named Inventor	Timmermans et al.
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**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		LEE, H.K., et al., Decreased mitochondrial DNA content in peripheral blood precedes the development of non-insulin-dependent diabetes mellitus, 42 Diabetes Research and Clinical Practice 161-67 (1998).	
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		WILLIAMS R.S., Mitochondrial Gene Expression in Mammalian Striated Muscle. Evidence That Variation in Gene Dosage is the Major Regulatory Event, J. Biol. Chem., 261 (26):12390-94 (1986).	
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